

REMARKS

The Official Action dated April 14, 2005 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claim 1 has been amended to clarify that the transparent or translucent portion is a portion of the housing, as set forth in the specification at page 8, lines 12-14. Additionally, claim 12 is added, support for which may be found in the specification, for example, at page 10, lines 12-15. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Claim 1-3 and 5-11 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner questioned if the housing or a portion of the housing was made of transparent or translucent material. This rejection is traversed and reconsideration is respectfully requested. Claim 1 clearly recites a transparent or translucent portion of the housing. Accordingly, at least a portion of the housing is transparent or translucent, but the entire housing is not required to be transparent or translucent. Thus, claims 1-3 and 5-11 particularly point out and distinctly claim the subject matter which Applicants regard as the invention in accordance with the requirements of 35 U.S.C. §112, second paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Claims 1-3, 10 and 11 were rejected under 35 U.S.C. §102(b) as being anticipated by the May et al U.S. Patent No. 5,602,040. Claims 7-9 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over May et al. The Examiner asserted that May et al teach a device containing a control zone loaded with an antibody that will bind to a labeled antibody from a first zone or containing an anhydrous

reagent that, when moistened, produces a color change or color formation. The Examiner further asserted that May et al teach the use of an absorbent sink and that the time indicator taught by May et al is located directly on the wicking member or is located on the wicking member and the wicking member is disposed on a test strip.

The Examiner also asserted that May et al specifically disclose that the spacial separation between the zones and the flow rate characteristics of the porous carrier material can be selected to allow adequate reaction time during which the necessary specific binding can occur and to allow the labeled reagent in the first zone to migrate through the carrier, whereby May et al recognize and teach variable positioning of the reagents, including the dye indicator. Finally, the Examiner asserted that claim 1 did not recite that the housing has a transparent or translucent portion and that May et al teach that the housing can be optional, with a nitrocellulose sheet sandwiched between two supporting sheets which can be transparent. Finally, the Examiner asserted that May et al teach that the window or aperture locations are lined with transparent plastic to allow observation of the results.

However, Applicants submit that the assay devices and methods defined by claims 1-3 and 7-11 are neither anticipated by nor rendered obvious over May et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, according to claim 1, the assay device of the present invention comprises an elongate flow matrix, a wicking member, an indicator, and a housing. The elongate flow matrix allows lateral transport of fluid therethrough by capillary action and comprises a liquid application zone and a detection zone downstream of the liquid application zone. The detection zone has an immobilized capture agent capable of directly or indirectly binding to an analyte in an aqueous sample. The wicking member is at the downstream end of the flow matrix and has an upstream end and a downstream end. The indicator is downstream of the detection zone for indicating when liquid applied in the liquid application

zone has reached the indicator. The indicator comprises an indicator substance or substance combination which is capable of exhibiting a visible color change when hydrated by the aqueous sample. The indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends of the wicking member, thereby permitting variation of the time elapsing from the application of liquid to the liquid application zone until the indicator substance or substance combination changes color. The housing encloses the flow matrix and the wicking member, and the indicator is included on an inner side of the housing at a transparent or translucent portion of the housing. Thus, the assay device is adaptable for use in different assays requiring different liquid travel times by placing the indicator at a desired position between the upstream and downstream ends of the wicking member along the translucent/transparent portion of the housing.

May et al disclose an analytical test device which, as described at column 5, beginning at line 8, may include a control zone to convey an unrelated signal to the user that the device has worked. May et al disclose that the control zone can be loaded with an antibody that will bind to the labeled antibody or may contain an anhydrous reagent that, when moistened, produces a color change or a color formation. Further, the control zone could contain immobilized analyte which will react with excess labeled reagent. May et al disclose that the control zone is located on the same test strip as a detection zone (i.e., strip 206, strip 510, or strip 606 in the embodiments of Figs. 6, 8 and 11, respectively) and is visible through a window (i.e., window 205, aperture 509, or aperture 604 in the embodiments of Figs. 6, 8 and 11, respectively).

Initially, Applicants note that while the assay device of claim 1 requires an elongate flow matrix, a wicking member at the downstream flow of the flow matrix, and an indicator arranged in contact with the wicking member at a variable position between the upstream and downstream ends of the wicking member, May et al merely disclose a control zone on the

same test strip as a detection zone. For example, in Figs. 6 and 7, the control zone 210 is on the same test strip as the detection zone 209, in Figs. 8 and 9, the control zone visible through aperture 509 is on the same test strip as the detection zone visible through aperture 508, and in Figs. 11 and 12, the control zone visible through window 604 is on the same test strip as the reaction zone visible through window 603. Applicants find no teaching or suggestion by May et al relating to an indicator in contact with a wicking member which is, in turn, downstream of a flow matrix having a detection zone, particularly with the indicator arranged at a variable position between the upstream and downstream ends of the wicking member.

Further, Applicants find no teaching or suggestion by May et al that the control zone may be variably arranged downstream of a flow matrix or a detection zone. While the Examiner asserts that because May et al teach that spacial separation between the various zones and the flow rate characteristics of the porous carrier material can be selected to allow adequate reaction times during which necessary specific binding can occur and to allow the labeled reagent to migrate through the carrier, May et al provide no teaching or suggestion for arranging the control zone at a variable position, particularly since May et al disclose that the control zone merely confirms that the sample has permeated the test strip (column 5, lines 13-14).

Moreover, Applicants find no teaching or suggestion by May et al that any portion of a housing enclosing both a flow matrix and a wicking member should be formed with a transparent or translucent portion, particularly with an indicator located on an inner side of the housing at the transparent or translucent portion of the housing, as is clearly required in the assay device of claim 1. To the contrary, May et al teach away from such an assay device in the figures which show casings with a relatively small control zone window or aperture 205 (Fig. 6), 509 (Fig. 8) and 604 (Fig. 11), without any teaching of means for viewing an indicator placed anywhere other than at the casing window or aperture.

On the other hand, in the assay device of the present invention, wherein the indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends of the wicking member, and at a translucent/transparent portion of the housing, the indicator has a wide range of positions along the wicking member, visible through the translucent/transparent housing portion. For example, with reference to Fig. 3, the position of the indicator 14 may be varied along the length of the wick 13 as desired depending on the particular assay which is to be conducted. Applicants find no teaching or suggestion by May et al in this regard.

In the Official Action, the Examiner asserted that even if the housing of claim 1 has a portion that is transparent or translucent, such a portion is obvious over the teaching of May et al because May et al teach that the housing can be optional and the nitrocellulose sheet carrying the various zones can be sandwiched between two supporting sheets of plastic which can be transparent.

Applicants disagree with the Examiner's assertions. First, it is clear from claim 1 that a portion of the housing is transparent or translucent. The Examiner's assertion that such a housing is obvious over the teaching of May et al is not relevant to rejections under 35 U.S.C. §102. Moreover, the May et al embodiment which omits a housing cannot anticipate or render obvious the presently claimed device which includes a housing. Further, the embodiment of May et al employing two supporting sheets, for example transparent plastic sheets, does not teach or suggest a device including a housing enclosing a flow matrix and a wicking member, as required by present claim 1. Two supporting sheets of plastic clearly do not teach one of ordinary skill in the art to use a housing enclosing a flow matrix and a wicking member.

Finally, in the Official Action, the Examiner asserted that May et al teach that the window or aperture locations are lined with transparent plastic to allow observation of results, thereby teaching that the housing is provided with a transparent or translucent portion.

However, Applicants disagree. That is, May et al merely teach that the test strip 510 may be backed by a supporting strip 511 formed of transparent moisture-impermeable plastics material to act as a seal against ingress of moisture from outside the housing through apertures 508 and 509, and, if desired, the apertures may be provided with transparent inserts to insure greater security against ingress of extraneous moisture. First, May et al do not disclose a housing having a transparent or translucent portion. To the contrary, May et al, at best, teach a housing having windows provided with a further element, namely a transparent sealing film. Further, Applicants again note that the apertures taught by May et al provide no viewing of a wicking member at the downstream end of a flow matrix (i.e., the test strip of May et al), and therefore provide no viewing of an indicator arranged at a variable position between upstream and downstream ends of a wicking member, as required by claim 1. Thus, May et al do not teach or suggest the presently claimed device.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference, *In re Robertson*, 49 U.S.P.Q.2d 1949, 1950 (Fed Cir. 1999). In view of the failure of May et al to teach an indicator arranged in contact with a wicking member at a variable position between the upstream and downstream ends, particularly in combination with a housing having a translucent or transparent portion at which the indicator is arranged, May et al do not disclose each and every element as set forth in the present claims. Thus, May et al do not anticipate the present claims under 35 U.S.C. §102.

Moreover, it is error to find obviousness where references diverge from and teach away from the invention at hand, *In re Fine*, 5 U.S.P.Q.2d 1596, 1599 (Fed. Cir. 1988). As

May et al fail to teach or suggest varying the position of the control zone along a wicking member, particularly at a location wherein the housing is provided with a translucent or transparent portion, and rather teach a control zone on a test strip at a set window or aperture location, May et al teach away from the presently claimed assay device. Thus, May et al do not render the present claims obvious.

It is therefore submitted that the assay device and methods defined by claims 1-3 and 7-11 are neither anticipated by nor rendered obvious over May et al, whereby the rejections under 35 U.S.C. §§ 102 and/or 103 have been overcome. Reconsideration is respectfully requested.

Finally, claims 5 and 6 were rejected under 35 U.S.C. §103(a) as being unpatentable over May et al in view of the Gattiglia U.S. Patent No. 6,655,315. The Examiner asserted that it would have been obvious to use an indicator label-soaked support as taught by Gattiglia in the device of May et al.

However, Applicants submit that the assay devices defined by claims 5 and 6 are nonobvious over and patentably distinguished from the combination of May et al and Gattiglia. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

The deficiencies of May et al with respect to claim 1, from which claims 5 and 6 depend, are discussed in detail above. These deficiencies apply equally as well to the devices defined by claims 5 and 6 which respectively recite that the indicator includes a hygroscopic substance and a filler substance. The deficiencies of May et al are not resolved by Gattiglia. That is, Gattiglia discloses moisture indicators which comprise copper chloride or another salt capable of releasing copper and chloride ions, and synergistic salts containing chloride ions which may be hygroscopic on a suitable support. The support may be an amorphous silica or silica gel, a solid paper support, or a bentonite or calcium sulfate for making pellets.

However, Applicants find no teaching or suggestion or Gattiglia relating to an assay device as presently claimed, particularly including a flow matrix, a wicking member, an indicator and a housing as recited in claim 1, wherein the indicator is arranged in contact with the wicking member at a variable position between the upstream and downstream ends of the wicking member and on an inner side of the housing at a transparent or translucent portion of the housing. In fact, Applicants find no teaching or suggestion by Gattiglia relating to assay devices or housings suitable for use therein. Thus, Gattiglia does not resolve the deficiencies of May et al, whereby the devices of claims 5 and 6 are nonobvious over and patentably distinguishable from the combination of May et al in view of Gattiglia. It is therefore submitted that the rejection of these claims under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 102, 103 and 112, second paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



Holly D. Kozlowski
Registration No. 30,468
Attorney for Applicant(s)
Dinsmore & Shohl LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8568